UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,687	08/07/2006	Isabelle Rault	33379-US-PCT	4963

74550 7590 04/24/2009

FRANK A. SMITH
Novartis Consumer Health, Inc.
200 Kimball Drive
OTC PATENT DEPARTMENT - 5TH FLOOR
Parsippany, NJ 07054-0622

EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	**PAPER NUMBER**
1618	

MAIL DATE	DELIVERY MODE
04/24/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/572,687	RAULT ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9 - 16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9 - 16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *12/15/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed January 23, 2009, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Specification

1. The abstract of the disclosure was objected to because it referred to the purported merits or speculative application of the invention and the title was objected to because it was not descriptive. Both of these objections are MAINTAINED.

Applicants argue that the purpose of the abstract is to enable the public to quickly determine the gist of the disclosure and the current abstract does that. The words of the title are found verbatim in claim 1. Nothing more is required notwithstanding the Examiner's stylistic choice of alternative language.

The MPEP 608.01(b) states that content of the abstract should not refer to the purported merits of the application, which the instant application does. The invention to which the claims are directed is not a general film coated tablet, but are strictly limited to the coating of diclofenac tablets. Therefore a new title is still required as the current title is not descriptive of the invention being claimed (see MPEP 606.01).

Claim Rejections - 35 USC § 112 – 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 15 and 16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear on what basis the weight/weight percentages of the active ingredients are calculated. The coating comprises 60 – 70% HPMC, 8 – 12% stearic acid, 5 – 15% microcrystalline cellulose (MCC) and 10 – 20% titanium dioxide of the coating." This underlined phrase "of the coating" seems to imply that the percentages are based on the weight of the coating alone, but ambiguity remains as to how the percentages are calculated because of the phrasing of the claim.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 9 – 11, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. (US 6,558,701). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 12, 2008 and those set forth below.

Applicants traverse this rejection on the grounds that the teachings of Bartholomaeus et al. are totally irrelevant to the present inventions as it describes a multilayer table with two active ingredients and an internal separation layer, which is quite different from a coating. Coatings are only mentioned in plural and the single coating product produces a surprising and unexpected advantage. As the reference distinguishes between the separation layer and the coatings, the Examiner cannot

equate the two and there is nothing about these optional coatings other than their application by conventional processes. The amounts of MCC and HPMC are completely outside the scope of the corresponding compounds of the present invention. The identification of specific locations within Bartholomaeus et al. wherein suggestions for a variety of features (e.g., delete one of the two active ingredients, that the separation layer be applied to the optional coating)can be found is requested.

These arguments are not found persuasive. The instant claims use the open language of "comprising" and therefore the presence of other active ingredients andor layers in the dosage form are not excluded by the instant claims. Thus, the amendment of claim 1 to recite "a single film coating" layer does not distinguish the claims over the cited prior art. Applicant has not defined in the specification or the claims that the coating comprising hydroxypropyl methylcellulose, stearic acid and microcrystalline must be the outermost structure of the dosage form and/or that other layers or coatings cannot be applied over it. The composition of the applied layer, and not the label of "coating" or "separating layer" applied, is what must be evaluated to determine if the claims are patentable over the cited prior art. A separate layer containing HPMC, stearic acid and microcrystalline cellulose with a core containing diclofenac or a pharmaceutically acceptable salt thereof is disclosed by the cited prior art.

As discussed in more detail in the MPEP sections discussing *KSR International Co. vs Teleflex Ltd.* decision (e.g., MPEP 2141 Section I), the suggestion or motivation to combine need not be explicitly stated in the references. The knowledge of one of ordinary skill in the art at the time of the instant invention can also provide the requisite

motivation or suggestion. It is known that the amounts of excipients present in a dosage form will alter the final properties of the dosage form, such as the hardness and/or compressibility (see p 5 of the September 12, 2008 Office Action). The amount of the excipients can be varied to produce a tablet that can be formed in a repeatable manner with suitable hardness for a tablet dosage form that is also compatible with the other ingredients present in the composition. A suggestion or motivation to remove one of the two active ingredients is not required as the claimed invention does not require the removal of the tramadol from the compositions of Bartholomaeus et al. in order to be rendered obvious.

8. Claims 9 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. further in view of Humbert-Droz et al. (US 6,083,531). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 12, 2008 and those set forth below.

Applicant traverses this rejection on the grounds that the Examiner mistakenly identified the separating layer of Bartholomaeus et al. as optional coatings. The combination is deemed without merit because they are directed two totally different dosage forms. Bartholomaeus et al. discloses a multilayer tablets with two active ingredients while the dosage form of Humbert-Droz et al. is a homogenous mixture of four components selected for rapid disintegration, which cannot be coated as the coating would defeat the rapid dissolution. Other than both disclosing drug dosage forms, the two teachings are not at all related and there is no basis to combine.

These arguments are not persuasive. “Coating” and “separating layer” and labels and the constituents of a portion of the dosage form that does not contain diclofenac is the same in the instant claims and Bartholomaeus et al. While Bartholomaeus et al. and Humbert-Droz et al. relate to different dosage forms with different release profiles, the teachings of the two in regards to appropriate milligram dosages of the diclofenac salt active ingredient can be combined because as stated by Applicant, both documents relate to drug dosage forms of diclofenac.

9. Claims 9 – 11 and 13 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bartholomaeus et al. as applied to claims 9 – 11, 13 and 14 above, and further in view of De Haan et al. (US 2006/0051420) and SEPIFILM® LP Product page (accessed 4/10/09).

Bartholomaeus et al. discloses a multi-layered dosage from with a diclofenac layer surrounded by a layer comprised of MCC, HPMC and an excipient such as stearic acid.

Bartholomaeus et al. does not disclose a layer comprising 60 – 70% HPMC, 8 – 12% stearic acid, 5 – 15% microcrystalline cellulose (MCC) and 10 – 20% titanium dioxide (all percentages w/w).

De Haan et al. discloses a stabilized pharmaceutical dosage form provided with a coating (abstract). One film coating applied to the tablets is SEPIFILM® LP770, which consists of HPMC, stearic acid and talc (¶ [0052]). The SEPIFILM® LP770 product page indicates that a white version of the coating is also available, in contrast to the

clear version of the product, but both products decrease water vapor transmission rates (p 1 – top of 2). The instant specification (¶ [0018] of the PGPub) indicates that SEPIFILM® LP 770 White contains 60 – 70% HPMC, 8 – 12% stearic acid, 5 – 15% microcrystalline cellulose (MCC) and 10 – 20% titanium dioxide.

It would have been obvious to one of ordinary skill in the art to apply a moisture protective coating such as SEPIFILM® LP770 white to the pharmaceutical formulations taught by Bartholomaeus et al. One of ordinary skill would do so to protect the product from water vapor and to provide a tablet with a white appearance. Applicant has argued that the coatings of Bartholomaeus et al. are only optional and that a suggestion in Bartholomaeus et al. be provided for the inclusion of such a composition. "Optional" means left to one's choice or not required or mandatory. Thus, the description by Bartholomaeus et al. as to such coatings being something that may, but it not required, be included would indicate to one of ordinary skill in the art that those coatings could be included. The teachings of De Haan et al. and SEPIFILM® product information indicates that a coating can be applied to the dosage form to protect against water vapor.

10. Claims 9, 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. (WO 99/51209). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 12, 2008 and those set forth below.

Applicant requests clarification of the statutory basis for this rejection, assumed to be under 35 USC 103. The rejection itself is traversed on the grounds that the teachings of Ting et al. have no relevance to the present invention as it teaches a

compartment dosage form consisting of an innermost (when present) compartment of polymers but no active ingredient; a compartment for immediate release of an active ingredient with polymers; and a surrounding extended release compartment with active ingredient and both hydrophobic and hydrophilic polymers. The structure of the reference is completely different, there is no mention made of diclofenac potassium even though well over 100 compounds are listed, including many in the salt form. The argument by the Examiner of optimization of parameters is traversed because the Examiner only recites hardness and compressibility as a desired result, neither of which are presently claimed. Extended release from an outer component is also not one of the objectives of the present invention.

These arguments are not found to be persuasive. Paragraph 11 on p 7 of the September 12, 2008 Office Action states that the claims are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. so the Examiner did provide the statutory basis of the rejection.

The structures recited in the instant claims are described by Ting et al. as a tablet core with active ingredient surround by a layer comprising HPMC, MCC and hydrogenated vegetable oil, the latter being functionally equivalent to stearic acid (see p 7 – 8 of the September 12, 2008 Office Action). The layer surrounding the diclofenac core of the instant claims comprises HPMC, MCC and stearic acid.

Ting et al. is concerned with a generalized dosage form that can be used with a variety of active agents. The length of the list of active ingredients dose not negate the fact the Ting et al. clearly envisions a dosage form of diclofenac sodium for use in the

dosage form. This rejection of claim 2, analogous to current 10 which required diclofenac potassium, in regards to this piece of cited art has been withdrawn.

As discussed in more detail in the MPEP sections discussing *KSR International Co. vs Teleflex Ltd.* decision (e.g., MPEP 2141 Section I), the suggestion or motivation to combine need not be explicitly stated in the references. The KSR decision also stated that one of the errors made by the Federal Circuit made were in only looking at the problem that the patentee was trying to solve. Thus an optimization of parameters to provide optimal hardness, compressibility or the release rate of the active ingredient can still be applied even though that was not the problem that the patentee was trying to solve. One of ordinary skill in the art routinely varies the amount of the excipients in the dosage form to alter various physical properties of the final dosage and thus optimization of the exact amounts of the ingredients disclosed by the prior art as being present in the composition is within the skill of one of ordinary skill in the art that would be routinely optimized.

11. Claims 9 – 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. further in view of Humbert-Dolz et al. (US 6,083,531). This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed September 12, 2008 and those set forth below.

Applicant traverses this rejection on the grounds discussed above in regards to these references and assumes that the US'701 was also relied upon. There is no basis for combining these references merely because they are all concerned with the tableting

art and disclose similar or overlapping compounds is not the basis for a rejection under the statute.

These arguments are not persuasive. The statement of rejection in the first paragraph of point 12 is correct and no a typographical error was made in the last paragraph of the point in mentioning the US '701 reference. Diclofenac in the potassium or sodium form, as well as the 12.5 mg dosage of diclofenac potassium are all taught by Dumbert-Holz et al. (see ¶ 4 of point 12, p 9). The references are not being combined merely because they all relate to the tableting art and disclose same or similar or overlapping components. Rather, Dumbert-Holz et al. teaches the use of an alternative salt form of the active ingredient and provides information on an appropriate dosage of the active ingredient, information which is lacking from Ting et al. That these two pieces of art are in the same field of endeavor as Applicant and the primary reference - the preparation of tablet dosage forms for active ingredients such as diclofenac, indicates that one of ordinary skill in the art would deem the information therein to be pertinent to the compositions being disclosed.

12. Claims 9 – 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ting et al. and Humbert-Droz et al. as applied to claims 9 – 14 above and further in view of Kurihara et al. (US 4,341,563) and the SEPIFILM® LP Product page (accessed 4/10/09).

As discussed in greater detail in the September 12, 2008 Office Action, Ting et al. and Humbert-Droz et al disclose a dosage form of diclofenac, in either the potassium or sodium salt form, surrounded by a layer comprising HPMC, stearic acid and MCC.

None of these references teach the inclusion or titanium dioxide or an amount of titanium dioxide 10 – 20% (w/w) along with the HPMC, MCC and stearic acid.

Kurihara et al. discloses the application of a protective coating to prevent degeneration or decomposition of the active ingredients that can contain titanium dioxide a coloring agent (col 4, ln 56 – 58).

The SEPIFILM® LP770 product page indicates that a clear and white version of the coating is available and both products decrease water vapor transmission rates (p 1 – top of 2). The instant specification (¶ [0018] of the PGPub) indicates that SEPIFILM® LP 770 White contains 60 – 70% HPMC, 8 – 12% stearic acid, 5 – 15% microcrystalline cellulose (MCC) and 10 – 20% titanium dioxide.

It would have been obvious to one of ordinary skill in the art, given the teachings of Kurihara et al. and the SEPIFILM® product page, to apply a coating such as SEPIFILM® to the diclofenac dosage form taught by Ting et al. and Humbert-Droz et al. One of ordinary skill in the art would have been motivated to apply a coating to exclude water vapor and produce a white tablet and would have reasonably expected success as Kurihara et al. and the SEPIFILM® product page teach the application of coatings to pharmaceutical dosage form for the protection of the dosage form and the active ingredient(s) contained therein.

Applicant argues that there is no motivation to combine Ting et al., Humbert-Droz et al. and Kurihara et al. as the first two references cannot be combined since no combination of the dosage form of Ting et al. (extended release outer compartment) and the uncoated four-component rapidly dissolving table of Humbert-Droz et al. could possibly lead to the coated tablet of the present invention. The disclosure of various ingredients in Kurihara et al. does nothing to cure the basic deficiency of the first two references.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, as discussed in greater detail above, the compartment dosages of Ting et al. can be combined with the teachings of Humbert-Droz et al. regarding the salt form and the dosage of diclofenac in the dosage form. The secondary references apply to strategies that can be used to optimize the stability of the active ingredient(s) present in the dosage forms and suitable combinations of ingredients that can be used in the pharmaceutical arts for this purpose.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW